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Andrew Thomas Fagan

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PATENT GROUP 2N

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EXAMINER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/014,883	<b>Applicant(s)</b> FAGAN ET AL.	
	<b>Examiner</b> VIVEK D. KOPPIKAR	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7,9-22,25-34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-22 and 25-34 is/are rejected.
- 7) ☒ Claim(s) 37-38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-2, 4-7, 9-22 , 25-34 and 37-38 have been examined in this application. This is a non-final office action in response to the Request For Continued Examination (RCE) filed on December 13, 2007.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: The word “biodevelopment” on Page 2, line 3 should be "biomedical development". Appropriate correction is required.

Claims 37 is objected to because of the following informalities: Claim 38 sets forth the limitation “wherein the patient identification metadata in the genomic metadata structure is used to link genomic information in the genomic data warehouse with data collected during the plurality of biomedical development phases.” The Office recommends claiming this limitation in a more active form so that the limitation has a function within the system of the invention.

Claims 38 is objected to as being dependent on an objected claim, Claim 37.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-2, 4-7, 9-22 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,949,999 to Song in view of US Patent Application Publication 2002/0087673 to Selkirk and in further view of US Patent Number 7,054,823 to Briegs and in further view of US Patent Application Number 2003/0028549 to Hartel and in even further view of US Patent Application 2002/0049738 to Epstein.

a database that stores data collected from the biomedical development phases (Song: Col. 5, Ln. 38-42);

at least one first graphical user interface connected to the database that collects data during the first biomedical development phase (Song: Col. 5, Ln. 27-31) (Song discloses that its software is adapted for product development processes regulated by the FDA which the examiner interprets to include biomedical or pharmaceutical processes); and

Song has the capability of producing and generating an audit trail of data (Song: Col. 2, Ln. 10-23).

It is the position of the Office that the following feature is inherent in Song: a plurality of graphical user interfaces for collecting data relating to the biomedical development phases, wherein the plurality of graphical user interfaces are specific to different ones of the biomedical development phases (Song: Col. 1, Ln. 48-50). (Note: Song discloses a the step of selecting a phase in the aforementioned cited portion. Therefore it is implicit that the invention of Song is adapted for a multi-phase process. In addition, in the aforementioned portion of Song, a plurality of users are disclosed and therefore, it is inherent that each user will have their own individual PC and each PC will have a graphical user interface. Therefore, Song discloses a plurality of graphical user interfaces).

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Song does not teach the following limitations and features which are taught by Selkirk:

wherein the metadata data structure of the first graphical user interface is defined based at least in part upon the first metadata data structure so that the first graphical user interface collects data points as well as first metadata that is to be stored within the first metadata data structure, said first metadata describing the collected data points and a (first) database including a first metadata data structure that describes the data collected during a first biomedical development phase (Selkirk: Section [0024]),

wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent development phase (Selkirk: Section [0024]). (Note: Selkirk does not explicitly teach that its metadata structure (in Section [0024]) is used for a biomedical development phase or that the metadata links are patient identification or study identification metadata, however, the Office takes the position that it is within the scope of Selkirk to use the invention in a biomedical development phase since the contemplated use of Selkirk is for applications involving metadata which include biomedical development phases).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the system of Song with the aforementioned features from Selkirk with the motivation of having a more enhanced means of storing and recovering data, as recited in Selkirk (Section [0024]).

The combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel do not teach the following limitation which is taught by the combined teachings of Briegs and Hartel:

wherein at least a portion of the data structure is configured to provide information for a subsequent biomedical development phase (Briegs: Figure 50 and Col. 39, Ln. 9-12). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel with the aforementioned teachings from Briegs with the motivation of having a means to inform the user that subsequent trials (visits) are still remaining, as recited in Briegs (Col. 39, Ln. 4-12).

In Briegs the “indication of whether any data is yet to be collected” does not relate to metadata structures, however, Hartel teaches the step of configuring metadata structures as needed (e.g. for subsequent phases) to provide their specific properties (Hartel: Section [0019]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel and Briegs with the aforementioned teachings from Hartel with the motivation of giving a user a means of customizing metadata structures, as recited in Hartel (Section [0019]).

The combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel do not teach the following features which are taught by US Patent Application Publication 2002/0049738 to Epstein (Section [0065]):

at least one of patient identification metadata and study identification metadata  
and

wherein the plurality of graphical user interfaces are configured to collect at least one of the patient identification metadata and the study identification metadata

(Note: Song teaches the feature of a plurality or “each of” the biomedical development phases (Song: Col. 1, Ln. 48-50)).

(Note: The Office would like to note that the claims do not require the following limitation to be present because it is preceded by the word "may": "such that the patient identification metadata or the study identification metadata may be used as linking data to indicate how the collected data interrelated with other data collected during the subsequent biomedical development phases." Therefore, the Office takes the position that even though Epstein does not explicitly disclose this feature it nevertheless reads on the last recited limitation of Claim 1).

(B) As per claim 2, in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel the biomedical development phases include phases selected from the group consisting of discovery phase, clinical studies phase, Food and Drug Administration (FDA) approval phase, product release phase, and combinations thereof (Song: Col. 2, Ln. 10-23).

(C) As per claims 3-8, 20-21 and 34, the combined system of Song in view of Selkirk in view of Briegs in view of Hartel teaches metadata data structures but does not expressly teach the specific data recited in claims 3-8, 20-21 and 34; however, these differences are only found in the non-functional descriptive material and are not functionally involved in the steps recited nor do they alter the recited structural elements. The recited method steps would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included these data types recited in the above mentioned claims with the motivation

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of providing a more comprehensive data analysis system to be used in the biomedical development phase.

(D) As per claim 9, the combined system of Song in view of Selkirk in view of Briegs in view of Hartel teaches a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase (Selkirk: Section [0024]). The motivation for modifying Song with these aforementioned features from Selkirk is the same as that was set forth in the rejection of Claim 1.

(E) As per claim 10, the combined system of Song in view of Selkirk in view of Briegs in view of Hartel comprises:

at least one second graphical user interface connected to the database that collects data during the second biomedical development phase (Song: Col. 5, Ln. 27-31), wherein structure of the second graphical user interface is defined based at least in part upon the second metadata data structure so that the second graphical user interface collects data points as well as second metadata that is to be stored within the second metadata data structure, said second metadata describing the collected data points (Selkirk: Section [0024]),

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the system of Song with the aforementioned features from Selkirk with the motivation of developing a system having the ability to process requests for reconfiguring different data repositories as recited in Selkirk (Section [0024]).



The combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel do not teach the following limitation which is taught by the combined teachings of Briegs and Hartel:

wherein at least a portion of the second metadata is determined based upon an issue which arises in a biomedical development phase that occurs approximately subsequently to the second biomedical phase (Briegs: Figure 50 and Col. 39, Ln. 9-12). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel with the aforementioned teachings from Briegs with the motivation of having a means to inform the user that subsequent trials (visits) are still remaining, as recited in Briegs (Col. 39, Ln. 4-12).

In Briegs the “indication of whether any data is yet to be collected” does not relate to metadata structures, however, Hartel teaches the step of configuring metadata structures as needed (e.g. for subsequent phases) to provide their specific properties (Hartel: Section [0019]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Selkirk in view of Briegs in view of Hartel and Briegs with the aforementioned teachings from Hartel with the motivation of giving a user a means of customizing metadata structures, as recited in Hartel (Section [0019]).

(F) As per claim 11, in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel the second biomedical development phase is a clinical studies phase (Song: Col. 10-23)(Note: Product development phases in the biomedical industry involve clinical studies), wherein the second metadata data structure includes data that specifies interrelationships between tests conducted during the second biomedical development phase (Selkirk: Section

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[0024]). The motivation for modifying Song with these aforementioned feature from Selkirk is the same as that set forth in the rejection of Claim 1.

(G) As per claims 12-15, in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel data links exist between the first metadata stored in the first metadata data structure and the second metadata stored in the second metadata data structure in order to form an audit trail (Selkirk: Section [0024] and Song: Col. 19-23). (Note: Relational databases, as disclosed by Selkirk, provide data links between various metadata sets).

In Song the audit trail is used during an FDA approval phase to determine a biomedical product development trail associated with the first and second biomedical development phases (Song: Col. 2, Ln. 10-23). (Note: The FDA audits the records dealing with various product development processes in part to approve the products).

The examiner takes the position that the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during the FDA approval phase to determine how tests were conducted during the second biomedical development phase. (Note: The purpose of the FDA audit is to examine the methodology of the tests).

(H) As per claims 16-18, in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel the examiner takes the position that the first biomedical development phase in Song is the discovery phase and the second development phase is the clinical studies phase (the discovery phase is commonly the first phase in a development process and the clinical studies phase is commonly the second phase in a development process), wherein at least a portion of the first metadata data structure is determined based upon an issue that arises in the FDA approval

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phase. (Song: Col. 2, Ln. 10-23). Song does not teach that the issue that arises in the FDA approval process that defines at least a portion of the first metadata data structure is an FDA requirement that patients be tested who are taking a predetermined medication. The examiner takes the position that it is well known in the biomedical and pharmaceutical industry that patients who are taking a predetermined medication be tested and at the time of the invention it would have been obvious for one of ordinary to have added this criteria to the development process in order to prevent patients who are taking a predetermined medication from having adverse reactions and in order to isolate or at least identify those patients which may be an aberrational affect on the data obtained from the biomedical development phase.

(I) As per claim 19, the examiner takes Official Notice that it is well known in the art to select the third party from another company division, a different company, the FDA or combinations thereof. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have selected these particular individuals with the motivation of having a pool of participants who are readily available to participate in the study.

(J) As per claims 22-29, these claims repeat features previously addressed in the rejection of claims 1-21 and are rejected on the same basis.

(K) As per claim 30, in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel the identifier is a uniform resource locator (URL) that identifies data and metadata as associated with the first biomedical project and owned by the first company (Selkirk: Claim 16). The motivation for making this modification to the system of Song is the same as that was set forth in the rejection of Claim 1.

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(L) As per claims 31-33, the examiner takes Official Notice that it is well known in the art to limit or allow the access rights of another entity to certain portions of the data and that access to portions of this data is protected by user names and passwords. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have added these features in the combined system of Song in view of Selkirk in view of Briegs in view of Hartel with the motivation of preventing unauthorized users from gaining access to the data and also for preventing an entity participating in the biomedical development phase from gaining access to data after its role in the biomedical phase had been completed.

***Response to Arguments***

5. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

***Allowable Subject Matter***

6. Claims 37-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

As per claim 37, the prior art of record does not teach or suggest patient identification metadata in the genomic metadata structure which is used to link genomic information in the genomic data warehouse with data collected during the plurality of biomedical development phases.

The non-patent reference "Taming the metadata monster" discusses the difficulties IT staffers face in linking together disparate metadata repositories (Text: Paragraph 1), however,

this non-patent reference does not disclose that the patient identification metadata in the genomic metadata structure is used to link genomic information in the genomic data warehouse with data collected during the plurality of biomedical development phases.

Claim 38 is objected to as being dependent on an objected claim, Claim 37.

***Conclusion***

7. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM. If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Examiner, Art Unit 3626